DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 24 1988

Re: Naftin
Docket No. 88E-0183

SOLICITOR

MAY 25 1988

U S PATENT &
TRADEMARK OFFICE

Charles E. Van Horn, Esq.
Deputy Solicitor, Solicitor's Office
U.S. Patent and Trademark Office
Washington, D.C. 20231

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U.S. Patent No. 4,282,251 filed by Sandoz Pharmaceuticals Corp. under the patent term extension provisions of 35 U.S.C. 156. The human drug product claimed by the patent is Naftin (naftifine hydrochloride) New Drug Application (NDA) 19-599.

A review of the Food and Drug Administration's official records indicates that Naftin, the product identified in the patent term extension application, was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records also indicate that it does represent the first permitted commercial marketing or use of the active ingredient, naftifine hydrochloride.

Our records also indicate that Naftin (naftifine hydrochloride) NDA 19-599, was approved on February 29, 1988, which makes the submission of the patent term restoration application received on April 28, 1988 timely within the meaning of 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d) we will then determine the applicable regulatory review period, publish that determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Gerald D. Sharkin
Patent and Trademark Affairs
Sandoz Pharmaceuticals
59 Route 10
E. Hanover, N.J. 07936